17-1480

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED, AMGEN USA, INC.,

Plaintiffs-Appellees,

v.

SANOFI, AVENTISUB LLC, REGENERON PHARMACEUTICALS INC., SANOFI-AVENTUS U.S., LLC,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware in Case Nos. 1:14–cv–01317–SLR, 1:14–cv–01349–SLR, 1:14–cv–01393–SLR, 1:14–cv–01414–SLR, Judge Sue L. Robinson.

BRIEF OF *AMICUS CURIAE* IN SUPPORT OF APPELLEES

Melissa Arbus Sherry
Michael A. Morin
Emily K. Sauter
LATHAM & WATKINS LLP
555 Eleventh St., NW
Suite 1000
Washington, DC 20004
(202) 637-2200
melissa.sherry@lw.com

March 30, 2017

Counsel for Amicus Curiae AbbVie Inc.

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

1. Full Name of Party represented by me:

   AbbVie Inc.

2. Name of Real Party in Interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

   AbbVie Inc.

3. Parent corporations and publicly held companies that own 10 percent or more of stock in the party:

   None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

   N/A.

Respectfully submitted,

/s/ *Melissa Arbus Sherry*

Melissa Arbus Sherry
LATHAM & WATKINS LLP
555 Eleventh St., NW
Suite 1000
Washington, DC 20004
(202) 637-2200
melissa.sherry@lw.com

March 30, 2017

Counsel for Amicus Curiae AbbVie Inc.

TABLE OF CONTENTS

Page

CERTIFICATE OF INTEREST i

TABLE OF AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 2

ARGUMENT 4

I. There Is No Basis For Treating Published Patent Applications Differently Than Issued Patents Under § 102(e). 4

A. This Court's Holding in *Drinkware* Applies Equally to Published Patent Applications 5

B. Neither *Wertheim* Nor § 122 Justify Differential Treatment 7

C. The Relevant Statutory History Supports Equal Treatment 10

D. The PTO Has Repeatedly Confirmed That *Drinkware* Applies Equally to Published Patent Applications 15

II. The District Court's Award of Injunctive Relief Was Proper 16

A. *eBay* and General Principles of Equity Support a Balancing Approach 16

B. The Blanket Anti-Injunction Rule Sought By Sanofi Runs Counter to *eBay* 20

C. The Public Interest Supports the Injunction Issued Below 22

CONCLUSION 26

TABLE OF AUTHORITIES

Page(s)

CASES

Abdullah v. Obama,
753 F.3d 193 (D.C. Cir. 2014)..20

Ariosa Diagnostics, Inc. v. Illumina, Inc.,
Case IPR2014-01093, 2016 WL 354412 (P.T.A.B. Jan. 7, 2016,
appeal docketed, No. 2016-2388 (Lead) (Fed. Cir. July 26, 2016)........14, 15, 16

Ex parte Cropper,
Appeal 2014-001403, 2016 WL 3541264 (P.T.A.B. June 24, 2016)................15

Davis v. Pension Benefit Guaranty Corp.,
571 F.3d 1288 (D.C. Cir. 2009)..20

Dynamic Drinkware, LLC v. National Graphics, Inc.,
800 F.3d 1375 (Fed. Cir. 2015) ....*passim*

eBay Inc. v. MercExchange, LLC,
547 U.S. 388 (2006)..3, 18, 22, 24

FMC Corp. v. United States,
3 F.3d 424 (Fed. Cir. 1993) 17

Fox Film Corp. v. Doyal,
286 U.S. 123 (1932)...24

In re Giacomini,
612 F.3d 1380 (Fed. Cir. 2010) 15

Gustafson v. Alloyd Co.,
513 U.S. 561 (1995)...12

Hall v. United States,
132 S. Ct. 1882 (2012)...12

Hecht Co. v. Bowles,
321 U.S. 321 (1944)...17, 21

Page(s)

Home Instead, Inc. v. Florance,
721 F.3d 494 (8th Cir. 2013) 20

Hybritech Inc. v. Abbott Laboratories,
849 F.2d 1446 (Fed. Cir. 1988) 17

Ex Parte Mann,
Appeal 2015-003571, 2016 WL 7487271 (P.T.A.B. Dec. 21, 2016)..........10, 15

Miles v. Apex Marine Corp.,
498 U.S. 19 (1990)....................12

New Railhead Manufacturing, L.L.C. v. Vermeer Manufacturing Co.,
298 F.3d 1290 (Fed. Cir. 2002) 4

Physicians National House Staff Ass'n v. Fanning,
642 F.2d 492 (D.C. Cir. 1980)....................14

PowerOasis, Inc. v. T-Mobile USA, Inc.,
522 F.3d 1299 (Fed. Cir. 2008) 7

Presidio Components, Inc. v. American Technical Ceramics Corp.,
702 F.3d 1351 (Fed. Cir. 2012) 19, 20

Ex parte Robbins,
No. 2009-001866, 2009 WL 3490271 (B.P.A.I. Oct. 27, 2009)....................14

Robert Bosch LLC v. Pylon Manufacturing Corp.,
659 F.3d 1142 (Fed. Cir. 2011) 19

Sanofi-Synthelabo v. Apotex, Inc.,
470 F.3d 1368 (Fed. Cir. 2006) 26

South Dakota v. Yankton Sioux Tribe,
522 U.S. 329 (1998)....................13

Taniguchi v. Kan Pacific Saipan, Ltd.,
132 S. Ct. 1997 (2012)....................12

United Air Lines, Inc. v. McMann,
434 U.S. 192 (1977)....................14

Page(s)

United Industries Corp. v. Clorox Co.,
140 F.3d 1175 (8th Cir. 1998) 17

United States v. Oakland Cannabis Buyers' Cooperative,
532 U.S. 483 (2001)....................17

United States v. Philadelphia National Bank,
374 U.S. 321 (1963)....................13

United States v. United Mine Workers of America,
330 U.S. 258 (1947)....................14

United States v. Wise,
370 U.S. 405 (1962)....................14

WBIP, LLC v. Kohler Corp.,
829 F.3d 1317 (Fed. Cir. 2016) 22

Weinberger v. Romero-Barcelo,
456 U.S. 305 (1982)....................16, 17

In re Wertheim,
646 F.2d 527 (C.C.P.A. 1981)....................2, 7, 9, 11, 12

Wilson v. Gordon,
822 F.3d 934 (6th Cir. 2016) 20

Ex parte Yamaguchi,
88 U.S.P.Q.2d 1606, 2008 WL 4233306 (B.P.A.I. Aug. 29, 2008)....................14

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS

U.S. Const. art. I, § 8, cl. 8....................23

35 U.S.C. § 102(a) 8

35 U.S.C. § 102(e) 2, 4, 11

35 U.S.C. § 102(e) (Supp. V 1999)....................11

35 U.S.C. § 119(e) 2

Page(s)

35 U.S.C. § 119(e)(1)..6

35 U.S.C. § 122 ....7, 8

35 U.S.C. § 282(a) 6

Pub. L. No. 103-465, 108 Stat. 4809 (1994)...12

Pub. L. No. 106-113, 113 Stat. 1501A-521 (1999) 13

Pub. L. No. 112-29, 125 Stat. 299 (2011)...2, 13

37 C.F.R. § 1.213 9

OTHER AUTHORITIES

Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 Health Econ. 130 (2010)..25

Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. On Judiciary, 111th Cong. (2009), http://bit.ly/2ntGgs7 25

157 Cong. Rec. S1360 (daily ed. Mar. 8, 2011) 13, 14, 15

Joseph P. Cook et al., *Generic Utilization Rates, Real Pharmaceutical Prices, and Research and Development Expenditures*, NBER Working Paper 15723 (Feb. 2010), http://www.nber.org/papers/w15723.pdf..25

Joseph A. DiMasi et al., *The price of innovation: new estimates of drug development costs*, 22 J. Health Econ. 151 (2003) 24

Independent Institute, *The Drug Development & Approval Process*, FDAReview.org (2016), http://bit.ly/1OgWWF5 24

F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20 Health Affairs 216 (2001)........................25

INTEREST OF *AMICUS CURIAE*[1]

AbbVie Inc. is an innovative biopharmaceutical company that discovers, develops, and markets drugs for the treatment of many diseases, including HIV, hepatitis C, cancer, multiple sclerosis, Parkinson's disease, and immunological diseases. One of AbbVie's drugs, HUMIRA® (adalimumab), was the first fully-human antibody approved by the Food and Drug Administration. HUMIRA® has been used to treat over a million patients suffering from diseases as diverse as rheumatoid arthritis, psoriasis, and Crohn's disease.

Like the drugs at issue here, Repatha and Praluent, HUMIRA® is one of a growing category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. Biologics can treat diseases very effectively, but are especially difficult and expensive to develop and manufacture because of their complexity. AbbVie's experience with the development of HUMIRA® gives it a unique perspective on the costs and risks associated with the discovery and development of biologics. And AbbVie has developed and will continue to develop new biologics. AbbVie thus has a significant interest in ensuring a robust system of patent protection in which courts retain the equitable discretion to keep infringing products off the market.

---

[1] All parties have consented to the filing of this brief. *Amicus Curiae* certifies that no counsel for either party authored this brief in whole or in part, and that no party or other person made a monetary contribution to the brief's preparation or submission.

INTRODUCTION AND SUMMARY OF ARGUMENT

This amicus brief focuses on two issues in particular: (1) the application of *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) (*Drinkware*) to published patent applications; and (2) the district court's award of injunctive relief. On both, Amgen has the better of the argument.

First, Sanofi's argument that *Drinkware* should not apply to published patent applications asks this Court to treat published patent applications differently than issued patents for purposes of 35 U.S.C. § 102(e).[2] But nothing in this Court's decision in *Drinkware*, the relevant statutory provisions, or the statutory or legislative history justifies giving published patent applications such special treatment. *Drinkware*'s rationale that a reference can claim the benefit of a provisional application's earlier filing date only when it is entitled to claim such benefit under 35 U.S.C. § 119(e) is equally, if not more, applicable to published patent applications: the Patent and Trademark Office (PTO) never examines priority before publishing a patent application, and published patent applications have no presumption of validity. Moreover, the rule advocated by Sanofi would expand the scope of potentially invalidating secret prior art, counter to the Court of Customs and Patent Appeals' instruction in *In re Wertheim*, 646 F.2d 527

---

[2] Unless otherwise specified, §§ 102(e), 112, 119(e), and 122 refer to the version of 35 U.S.C. §§ 102(e), 112, 119(e), and 122 predating the 2011 Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, respectively.

(C.C.P.A. 1981) to limit the scope of invalidating secret prior art to only that which is authorized by law. The statutory history of §§ 102(e) and 119(e) further supports a consistent approach, and the only legislative "history" allegedly suggesting otherwise came many years after the fact and is both wrong and deserving of little weight. Finally, the PTO has repeatedly held that *Drinkware* applies to published patent applications. This Court should do the same.

Second, Sanofi's argument that the district court erred in awarding injunctive relief is contrary to general principles of equity and to the public interest. The traditional four-factor test for injunctive relief is one of flexibility and equitable balancing, where no one factor is dispositive. *eBay Inc. v. MercExchange, L.L.C.* reaffirmed those familiar principles of equity and simply held that they apply equally to patent cases. 547 U.S. 388, 390 (2006). If anything, it is Sanofi that is arguing for a categorical rule contrary to *eBay*. A rule that precludes district courts from enjoining the sale of pharmaceutical products (other than generics and biosimilars, presumably) cannot be squared with *eBay*. It would also have the effect of denying equitable relief to a broad class of patent holders, and in precisely those cases where strong patent protections are most valuable to the public. This Court should reject that approach.

ARGUMENT

I. THERE IS NO BASIS FOR TREATING PUBLISHED PATENT APPLICATIONS DIFFERENTLY THAN ISSUED PATENTS UNDER § 102(e)

The holding of *Dynamic Drinkware, LLC v. National Graphics, Inc.*, is clear: when a challenger seeks to use a reference claiming the benefit of an earlier provisional application's filing date as § 102(e) prior art, it must demonstrate that the reference is entitled to claim the benefit of the earlier filing date under § 119(e)(1). 800 F.3d 1375, 1378 (Fed. Cir. 2015). "In other words, the specification of the *provisional* must contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms, 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application." *Id.* (quoting *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)).

Sanofi asserts, however, that published patent applications should be treated differently than issued patents under § 102(e), and should *presumptively* be entitled to the claimed benefit of an earlier-filed provisional application's filing date. This is a distinction without a difference. Although *Drinkware* examined what is required to prove that an issued patent qualifies as § 102(e) prior art, its holding is equally applicable to published patent applications, which may also be § 102(e) prior art. *See* 35 U.S.C. § 102(e) ("A person shall be entitled to a patent unless—

. . . (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . . ."). And the applicable statutes, case law, and legislative history all counsel against adopting a special rule for published patent applications. The Court should reject Sanofi's argument and hold that the same burden of proof applies under § 102(e) regardless of whether the putative reference is a published patent application or an issued patent.

A. This Court's Holding in *Drinkware* Applies Equally to Published Patent Applications

Under the reasoning of *Drinkware*, published patent applications should be held to the same requirements as issued patents to qualify as § 102(e) prior art.

First, *Drinkware* explained that "because the PTO does not examine provisional applications as a matter of course," presuming a patent is entitled to claim the benefit of an earlier-filed provisional application's filing date is "not justified." 800 F.3d at 1380. This rationale applies with even more force to published patent applications, since the PTO does not examine provisional applications at all—much less as a "matter of course"—when a non-provisional patent application is filed or published.

Second, *Drinkware* explained that the only basis for giving a reference priority to the filing date of an earlier-filed provisional application is § 119(e)(1), which expressly includes requirements to claim priority to the filing date of an earlier-filed provisional application. *Drinkware*, 800 F.3d at 1378. Specifically, § 119(e)(1) provides:

> An application for patent filed under section 111(a) or section 363 of this title for an invention *disclosed in the manner provided by the first paragraph of section 112 of this title* in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, *shall have the same effect, as to such invention, as though filed on the date of the provisional application* filed under section 111(b) of this title . . . .

35 U.S.C. § 119(e)(1) (emphases added). That same statute is also the only reason a non-provisional patent *application* can claim the benefit of an earlier-filed provisional application's filing date. Nothing in § 119(e)'s text would support a conclusion that a published patent application has a *presumptive* entitlement to the benefit of a provisional application's filing date. If there is no basis in §§ 102(e) or 119(e) to allow challengers to assert that a patent is entitled to claim the benefit of a provisional application's filing date without proving that § 119(e)(1) is satisfied, there is also no basis to allow them to assert that a published patent application is entitled to claim that same benefit, without satisfying § 119(e)(1).

Third, *Drinkware*'s rationale weighs even more strongly in favor of requiring published patent applications to meet § 119(e)(1)'s requirements to claim benefit to a provisional application's filing date. Unlike issued patents, published patent applications enjoy no presumption of validity. *See* 35 U.S.C. § 282(a) ("A *patent* should be presumed valid." (emphasis added)). And unlike issued patents, where the PTO may have examined whether the claims had sufficient written description and enablement support in the provisional application,[3] the PTO does not examine whether a patent application's claims have sufficient § 112 support before publishing it. Accordingly, published patent applications should be required to meet at least the same—if not additional—requirements to prove entitlement to an earlier filing date. *See, e.g.*, *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008) ("When neither the PTO nor the Board has previously considered priority, there is simply no reason to presume that claims in a [continuation-in-part] application are entitled to the effective filing date of an earlier filed application. Since the PTO did not make a determination regarding priority, there is no finding for the district court to defer to.").

B. Neither *Wertheim* Nor § 122 Justify Differential Treatment

Sanofi relies heavily on the Court of Customs and Patent Appeals' discussion of "secret" prior art in *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981) to justify the differential treatment of published patent applications and issued patents. *See* Appellants' Br. 47-48. Sanofi also argues that 35 U.S.C. § 122 has eliminated the potential harms caused by secret prior art. Appellants' Br. 47. Neither argument withstands scrutiny.

---

3 For example, an Examiner may examine priority support in a provisional application to determine whether a reference qualifies as prior art in deciding whether to issue (or withdraw) a rejection.

As Sanofi acknowledges, *Wertheim* was concerned about "potentially invalidating prior art" that "could be secretly lurking in pending applications for years." *Id*. Because of the harm this "secret" prior art can cause even to diligent patent owners and applicants, *Drinkware*, *Wertheim*, and the cases they rely on have narrowly construed the scope of what can qualify as invalidating secret prior art. *E.g.*, *Wertheim*, 646 F.2d at 537 (explaining that the Court will extend the secret prior art doctrine "only as far as we are required to do"). Consistent with this principle, *Drinkware* and *Wertheim* required strict compliance with the statutory provisions of §§ 119(e)(1) or 120 for potential prior art references to claim the benefit of an earlier application's filing date for § 102(e) purposes. *Drinkware*, 800 F.3d at 1378-80; *Wertheim*, 646 F.2d at 537. That reasoning applies with equal force to published patent applications and issued patents. Adopting Sanofi's argument and allowing published patent applications to claim the benefit of an earlier filing date without requiring a showing of compliance with §§ 119(e)(1) or 120 is inconsistent with the principle that the scope of secret prior art should be narrowly construed.

Contrary to Sanofi's arguments (at 47), § 122 is inapposite. Although patent applications are generally published after 18 months under § 122, the issue here is not whether such published patent applications can be prior art references *as of their publication date*. They unquestionably can under 35 U.S.C. § 102(a).

Instead, the question is whether the filing date of a reference that was *at one point secret* should presumptively be given to a later published or issued reference claiming priority to the once-secret reference. This Court has already answered that question in the negative in concluding that a once-secret provisional application's filing date is not presumptively given to a later-issued patent claiming priority to it. *Drinkware*, 800 F.3d at 1380-81. There is no rational basis to treat published patent applications differently, or to conclude that, because many non-provisional patent applications can be used as prior art as of their publication dates, they should not have to comply with §§ 119(e)(1) or 120 when they claim the benefit of an earlier application's priority date.

Although § 122 may have effectively reduced the frequency with which a patent challenger must rely on § 102(e), it has not eliminated the existence of potentially invalidating secret prior art. Provisional applications can still remain secret for years, since a non-provisional can be filed up to 12 months after a provisional is filed, and are only made public 18 months after a non-provisional application is filed claiming priority back to it. Moreover, an applicant can still choose not to have a patent application published at the 18-month mark by, for example, certifying that the disclosed invention will not be the subject of an application filed in another country. *See* 37 C.F.R. § 1.213. For this and the other reasons discussed above, concerns about "secret prior art" live on.

Indeed, rather than supporting Sanofi's position, § 122 counsels in favor of treating published patent applications the same as issued patents under § 102(e), because not doing so would create an arbitrary procedural trap for the unwary practitioner and render *Drinkware* almost meaningless. As the Patent Trial and Appeal Board (PTAB) has explained, "[l]imiting *Dynamic Drinkware* to issued patents would create an arbitrary distinction where a claim could be invalid over a published patent application but *not* the issued patent, despite the published patent application and its issued patent having identical disclosures." *Ex Parte Mann*, Appeal 2015-003571, 2016 WL 7487271, *3 n.5 (P.T.A.B. Dec. 21, 2016). "The practical effect would be that examiners and accused infringers should always rely on published patent applications as prior art rather than issued patents." *Id.* As a result, *Drinkware* would apply only to unwary practitioners "who unknowingly (and quite reasonably) assume issued patents and published patent applications should be treated the same given their identical disclosures." *Id.* Such a perverse rule has little to commend it.[4]

C. The Relevant Statutory History Supports Equal Treatment

The statutory history of 35 U.S.C. §§ 102(e) and 119(e) also supports treating published non-provisional patent applications the same as issued patents.

---

[4] Indeed, in *Drinkware* itself, the asserted prior art patent had a corresponding published patent application (U.S. Patent Pub. No. 2004/0157011) that could have been asserted instead of the patent. Thus, if Sanofi's rule were correct, *Drinkware* could have come out the other way.

In 1999, Congress amended 35 U.S.C. § 102(e) to include published patent applications.[5] In so doing, Congress used virtually identical language to describe published patent applications as it did to describe the patent prior art references at issue in *Wertheim*:

§ 102(e) (as discussed in *Wertheim*)	**§ 102(e) (1999)**
A person shall be entitled to a patent unless— (e) the invention was described in *a patent granted on an application for patent* by another filed in the United States before the invention *thereof* by the applicant for patent . . . *Wertheim*, 646 F.2d at 532 (emphases added to show differences with 35 U.S.C. § 102(e) (1999)).	A person shall be entitled to a patent unless— (e) The invention was described in- (1) *an application for patent, published under section 122(b)*, by another filed in the United States before the invention by the applicant for patent . . . 35 U.S.C. § 102(e) (Supp. V 1999) (emphasis added to show differences with the § 102(e) provision at issue in *Wertheim*).

In the face of *Wertheim,* which had been settled law for 17 years, Congress's decision to use virtually identical language to describe published patent applications and issued patents strongly suggests that they should be treated the same.

Indeed, two cardinal rules of statutory interpretation both point in that direction. First, the "normal rule of statutory construction" is "that identical words used in different parts of the same act are intended to have the same meaning." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2004-05 (2012) (internal quotations marks omitted) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995)). Second, "[w]e assume that Congress is aware of existing law when it passes legislation." *Hall v. United States*, 132 S. Ct. 1882, 1889 (2012) (quoting *Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990)). To treat published patent applications differently than issued patents, this Court would need to interpret different parts of § 102(e) with virtually identical language as having different meanings and assume that Congress departed from governing law *sub silentio*. There is no reason to countenance such a departure from the traditional canons of construction.

---

[5] Congress has subsequently amended § 102(e), but did not amend the language shown here until passage of the AIA.

Similarly, even though Congress amended § 119(e) after this Court's decision in *Wertheim*, it never changed the requirement that an application's claims have § 112 written description and enablement support to claim the benefit of an earlier-filed provisional application.[6] *See, e.g.*, Pub. L. No. 103-465,

[6] Because §§ 102(e), 112, and 119(e) speak in terms of "an invention," as opposed to a "disclosure," it is clear that, like patents, the *claims* of a published patent application (not the disclosure) must have § 112 written description and enablement support in the provisional application. *See Drinkware*, 800 F.3d at 1378 (explaining that § 119(e) requires § 112 written description and enablement support for "the invention *claimed* in the *non-provisional* application" (citation omitted)); *Wertheim*, 646 F.2d at 537 ("We emphasize that the above noted statutes, §§ 102(e), 120, and 112, speak with reference to some specific *claimed* subject matter by use of the terms[, including the word "invention,"] emphasized.

§ 532(b)(1)(A), 108 Stat. 4809, 4985 (1994) (enacting § 119(e), which stated that "[a]n application for patent filed under section 111(a) . . . of this title *for an invention disclosed in the manner provided by the first paragraph of section 112* of this title . . . shall have the same effect, as to such invention, as though filed on the date of the provisional application" (emphasis added)); Pub. L. No. 106-113, § 4504, 113 Stat. 1501A-521, 1501A-564 (1999) (amending § 119(e) only to add additional language at the end requiring a specific reference to the earlier-filed provisional application during pendency to claim benefit of the provisional application's filing date). This too supports treating published patent applications the same as issued patents.

Sanofi, in contrast, relies exclusively on *subsequent* legislative history from the 2011 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 299 (AIA). Appellants' Br. 48 (quoting 157 Cong. Rec. S1360, S1369 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl)). As an initial matter, it is well established that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329, 355 (1998) (quoting *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 348-49 (1963)). Indeed, "[t]he Supreme Court has consistently admonished against reading the

---

It is axiomatic in patent law that questions of description, disclosure, enablement, anticipation, and obviousness can only be discussed with reference to a specific *claim* which identifies "*the invention*" referred to in the statutes." (emphases added)).

mindset of one Congress from the actions of a subsequent Congress." *Physicians Nat'l House Staff Ass'n v. Fanning*, 642 F.2d 492, 509 (D.C. Cir. 1980); *see also United Air Lines, Inc. v. McMann*, 434 U.S. 192, 200 n.7 (1977) ("Legislative observations 10 years after passage of the Act are in no sense part of the legislative history."); *United States v. United Mine Workers of Am.*, 330 U.S. 258, 281-82 (1947); *United States v. Wise*, 370 U.S. 405, 411 (1962).

But there is also another reason why this Court should reject Sanofi's invitation to travel down that hazardous path: the AIA legislative history on which Sanofi relies is just wrong. Senator Kyl's entire analysis is premised on the assumption that *Wertheim* was almost completely overruled. The Court's decision in *Drinkware* makes clear that this assumption is incorrect, *see* 800 F.3d at 1382 (citing *Wertheim*), and the authority on which Senator Kyl relied proves the same. The PTO has acknowledged that the two B.P.A.I. decisions he cited—*Ex parte Yamaguchi*, 88 U.S.P.Q.2d 1606, 2008 WL 4233306 (B.P.A.I. Aug. 29, 2008) and *Ex parte Robbins*, No. 2009-001866, 2009 WL 3490271 (B.P.A.I. Oct. 27, 2009) (cited at 157 Cong. Rec. S1369)—are no longer good law after *Drinkware*. *See Ariosa Diagnostics, Inc. v. Illumina, Inc.*, Case IPR2014-01093, 2016 WL 354412, at *11 (P.T.A.B. Jan. 7, 2016), *appeal docketed*, No. 2016-2388 (Lead) (Fed. Cir. July 26, 2016). And this Court has now explained that Senator Kyl's reading of *In re Giacomini*, 612 F.3d 1380 (Fed. Cir. 2010), was incorrect. *Compare* 157 Cong.

Rec. S1369 ("Moreover, these BPAI decisions' holding that a patent has a patent-defeating effect as of the filing date of the provisional application to which it claims priority was recently affirmed by the Federal Circuit in In re Giacomini, 612 F.3d 1380 (Fed. Cir. 2010)."), *with Drinkware*, 800 F.3d at 1380-81 ("Dynamic's reliance on *Giacomini* to argue for a presumption is misplaced. . . . Because Giacomini waived the argument that the Tran provisional application did not support the Tran patent, we did not reach the question whether the Tran patent was presumptively entitled to the benefit of the filing date of its provisional application.").

D. The PTO Has Repeatedly Confirmed That *Drinkware* Applies Equally to Published Patent Applications

Although *Drinkware* was decided less than two years ago, the PTO has already repeatedly confirmed that *Drinkware*'s holding is equally applicable to published patent applications. *See Ariosa*, 2016 WL 354412, at *11; *Ex Parte Mann*, 2016 WL 7487271, at *3; *Ex parte Cropper*, Appeal 2014-001403, 2016 WL 3541264, at *4 (P.T.A.B. June 24, 2016). As the PTO has explained, there is "no persuasive authority demonstrating that 35 U.S.C. § 119(e)(1)," which was the basis for *Drinkware*'s holding, "applies only to issued patents, and not published patent applications." *Ariosa*, 2016 WL 354412, at *11; *see also Ex Parte Mann*, 2016 WL 7487271, at *3 ("[B]oth statute and case law suggest the holding in

Dynamic Drinkware applies equally to any application, regardless of whether a published application or an issued patent.”).

In fact, the PTO has already considered and rejected the same arguments Sanofi makes here. Like Sanofi, the *Ariosa* petitioner argued that since *Drinkware* and *Wertheim* dealt only with issued patents, their holdings cannot apply to published patent applications. *Compare Ariosa*, 2016 WL 354412, at *10, *with* Appellants' Br. 46-48. And the *Ariosa* petitioner cited the same two PTO decisions and subsequent legislative history that Sanofi relies on here.[7] *Compare Ariosa*, 2016 WL 354412, at *10, *with* Appellants' Br. 48. While the PTO's decisions are obviously not binding on this Court, their reasoning is both instructive and persuasive.

II. THE DISTRICT COURT'S AWARD OF INJUNCTIVE RELIEF WAS PROPER

A. *eBay* and General Principles of Equity Support a Balancing Approach

Injunctive relief is a creature of equity, and "[t]he essence of equity jurisdiction" has always "been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case." *Weinberger v.*

---

[7] Remarkably, Sanofi cites to two pre-*Drinkware* PTO decisions (*Yamaguchi* and *Robbins*) for the proposition that "the PTO has recognized" that "the reasoning of *Wertheim* does not apply to published applications" (Appellants' Br. 48), and ignores the multiple post-*Drinkware* decisions (*e.g.*, *Ariosa*, *Mann*, and *Cropper*) in which the PTO specifically applied *Drinkware* to published patent applications.

Romero-Barcelo, 456 U.S. 305, 312 (1982) (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944)). The traditional four-factor test for injunctive relief is accordingly one of "[f]lexibility," not "rigidity." *Id.* (quoting *Hecht Co.*, 321 U.S. at 329). And weighing the four factors has never been a "mechanical[]" exercise. *Id.* at 313.

As is inherent in the nature of equitable discretion, "[n]o one factor, taken individually, is necessarily dispositive." *FMC Corp. v. United States*, 3 F.3d 424, 427 (Fed. Cir. 1993); *see also, e.g., United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1179 (8th Cir. 1998) ("No single factor in itself is dispositive . . . ."). Although a party seeking an injunction "must establish a right thereto in light of [those] four factors," *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988), plaintiffs do not need to "establish[]" that they are entitled to relief as to *each* factor. *Id.* at 1457-58. Specifically, it is the court's job to "consider[]" the balance of equities and the public interest in the exercise of its discretion. *Id.* And even those considerations are contingent on the "necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312. "*To the extent* the district court considers the public interest and the conveniences of the parties, the court is limited to evaluating how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 498 (2001) (emphasis added).

Sanofi takes issue with this long tradition of equitable balancing. It argues that the district court erred when it issued an injunction without finding that the public interest supported injunctive relief. In Sanofi's view, an injunction is categorically unavailable unless each and every equitable factor weighs in favor of the plaintiff. *See* Appellants' Br. 59. Sanofi claims to find this checklist approach to the grant of an injunction in the Supreme Court's decision in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006). But *eBay* established no such rule.

In *eBay*, the Court simply held that the "familiar principles" of equity that govern the grant of an injunction "apply with equal force to disputes arising under the Patent Act." *Id.* at 391. The Court reaffirmed that injunctive relief lies within a court's "equitable discretion" and cannot be reduced to "categorical rule[s]." *Id.* at 391, 393; *see id.* at 394-95 (Roberts, C.J., concurring); *id.* at 395-96 (Kennedy, J., concurring). The Court repeatedly emphasized that it was applying "familiar," "traditional," and "well-established principles of equity." *Id.* at 391, 393-94. And it specifically cited *Romero-Barcelo* for those principles—which, as noted above, made clear that courts should weigh the balance of equities and the public interest in its equitable discretion. *Id.* at 391; *see also id.* at 395 (Roberts, C.J., concurring).

This Court and other courts of appeals have thus continued to weigh the merits of injunctive relief using the flexible balancing approach that *eBay* counseled. Take the case of *Robert Bosch LLC v. Pylon Manufacturing Corp.*, 659 F.3d 1142 (Fed. Cir. 2011), for example. This Court held that a permanent injunction should issue even though Bosch, the plaintiff, had failed to show that the public interest would not be disserved by an injunction. *See id.* at 1156. The Court explained that, "[a]lthough this final factor [did] not favor either party, the remaining considerations [led] to only one reasonable conclusion: that Bosch ha[d] shown that it [was] entitled to a permanent injunction." *Id.* It is precisely because "a district court should *balance* these equitable considerations," *id.* at 1157 (emphasis added), and not treat any one factor as determinative, that injunctive relief was deemed appropriate. Judge Bryson, in partial dissent, agreed: "Whether Bosch is entitled to injunctive relief is a fact-intensive inquiry that requires a careful balancing of competing equitable concerns, none of which is dispositive." *Id.* at 1157 (Bryson, J., dissenting in part).

This Court tacitly affirmed that principle in *Presidio Components, Inc. v. American Technical Ceramics Corp.*, 702 F.3d 1351 (Fed. Cir. 2012). There the Court reversed the denial of a permanent injunction after finding that the district court clearly erred in finding no irreparable injury. *Id.* at 1364. But it did so without disturbing the district court's conclusion that "the public interest tipped in [the non-movant's] favor." *Id.* at 1362. Rather than treating each factor as an independent barrier to injunctive relief, this Court sent the case back to the district court for a "re-weighing" of the four factors. *Id.* at 1364.

Other courts have continued to hold likewise in the wake of *eBay*. In the D.C. Circuit, for example, the plaintiff has the burden of showing that "all four factors, *taken together*, weigh in favor of the injunction." *Abdullah v. Obama*, 753 F.3d 193, 197 (D.C. Cir. 2014) (emphasis added) (citation omitted); *see also Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291-92 (D.C. Cir. 2009). Just last year, the Sixth Circuit noted that it must "balance four factors in deciding whether to issue a preliminary injunction," and that an injunction should issue when, "*overall*, the four . . . factors weigh in favor of granting the injunction." *Wilson v. Gordon*, 822 F.3d 934, 952, 958 (6th Cir. 2016) (emphasis added). And the Eighth Circuit recently reiterated that, when it comes to granting a preliminary injunction, "no single factor is determinative." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013) (citation omitted). Sanofi's effort to make the public-interest factor dispositive, such that it would trump even strong showings on the other three factors, runs contrary to these longstanding equitable principles.

B. The Blanket Anti-Injunction Rule Sought By Sanofi Runs Counter to *eBay*

Against the backdrop of equitable balancing and discretion, it is Sanofi that asks for that which *eBay* expressly forbids: a special, categorical rule for new pharmaceuticals. In Sanofi's view, district courts simply cannot enjoin the sale of pharmaceuticals (other than generics and biosimilars, presumably) because that necessarily disserves the public interest which, Sanofi argues, is dispositive. *See* Appellants' Br. 61 (describing an injunction under these circumstances as "forbidden fruit"). Sanofi's proposed exception, which would categorically deny injunctive relief against infringing, non-generic pharmaceuticals, is squarely counter to traditional standards of equity and to *eBay*.

As noted above, "discretion" and "[f]lexibility" are the key characteristics of equity. *Hecht Co.*, 321 U.S. at 329. Sanofi rightly points out that the "cardinal command" of equity courts is to do justice, *i.e.*, to "do equity." Appellants' Br. 60 (quoting *Hecht Co.*, 321 U.S. at 329). But the justice dispensed at equity is not a social justice, writ large. Rather, it is an "instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims." *Hecht Co.*, 321 U.S. at 329-30. This reconciliation will differ from case to case, as varying circumstances yield varying equities. In order to accomplish justice among the parties, and between the parties and the public, courts must have the power to "mould each decree to the necessities of the particular case." *Id.* at 329. Without flexibility, a court cannot do equity.

This is the principle that *eBay* vindicated. A portion of the *eBay* decision that is, perhaps, discussed less often is the Court's rejection of the categorical reasoning of the *district court* which had *denied* injunctive relief. The Court explained that, in denying such relief, the district court had adopted "certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases." *eBay*, 547 U.S. at 393. That too ran contrary to "traditional equitable principles" which do not permit "such broad classifications." *Id.* Sanofi's insistence that this Court should institute a special rule prohibiting injunctive relief in cases involving infringing, non-generic pharmaceutical products plainly contradicts the core teaching of *eBay*. As this Court very recently noted, in light of *eBay*, no court may craft "a categorical rule denying permanent injunctions for life-saving goods, such as many patented pharmaceutical products." *WBIP, LLC v. Kohler Corp.*, 829 F.3d 1317, 1343 (Fed. Cir. 2016). Equitable balancing, not rigid rulemaking, guides the question whether Amgen was entitled to injunctive relief here.

C. The Public Interest Supports the Injunction Issued Below

If the district court committed any error, it was the failure to properly assess the public-interest factor. A discussion of the public interest that does not recognize the substantial benefits that accrue from the equitable enforcement of patent rights is incomplete. Courts have long provided for injunctive relief in cases of patent infringement because significant public benefits often flow from a patent owner's ability to temporarily exclude infringing products from the marketplace.

Indeed, without such protection, the public may not have the benefit of any lifesaving drugs. Injunctive relief in this case *is* in the public interest.

In the nature of its public benefit, a biologic like Repatha is similar to any other patented product. Although the existence of the patent means that, in the short run, the public pays more than it otherwise would for the product in competitive conditions, the public reaps the rewards of innovation in the long run. This tradeoff is not new or controversial. It is embedded in the constitutional language that authorizes our patent laws. *See* U.S. Const. art. I, § 8, cl. 8 (giving Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their . . . Discoveries"). Sanofi's amici argue that injunctive relief should be unavailable here because it will temporarily reduce consumer choice and raise the cost of PCSK9 inhibitors. *See* Brief for Amici Curiae AARP and AARP Foundation at 7-9; Brief for Amici Curiae Dr. Luis Aparicio et al. at 22. But that is the whole point of patent protection. Injunctions give effect to the patent laws by providing patent owners with the "exclusiv[ity]" envisioned by the Constitution. This exclusivity is critical to encouraging the chemical and biological research necessary to bring innovative—and lifesaving—pharmaceutical treatments to market. Because weak patent protection will have a severe impact on the availability of new biologics like

Repatha and Praluent, the public's interest in vigorous enforcement of the patent laws is especially strong here.

The Supreme Court recognized in *eBay* that, although there can be no presumption in favor of an injunction in patent-infringement cases, the right of a patent holder is "the right to exclude others from using his property." 547 U.S. at 392 (quoting *Fox Film Corp. v. Doyal*, 286 U.S. 123, 127 (1932)). Historically, patent owners seeking to protect their rights have sought injunctive relief because of the "difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee's wishes." *Id.* at 395 (Roberts, C.J., concurring). Thus, "[f]rom at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases." *Id.*

The need for injunctive relief is especially pronounced in the context of pharmaceuticals, and with biologics in particular. The development of innovative, marketable pharmaceuticals is time-consuming and staggeringly expensive. Only 8% of drug candidates ever make it to market, and such efforts can take up to 19 years. *See* Independent Institute, *The Drug Development & Approval Process*, FDAReview.org (2016), http://bit.ly/1OgWWF5. A widely-cited 2003 study estimated the average cost of new drug development to be roughly $800 million. *See* Joseph A. DiMasi et al., *The price of innovation: new estimates of drug* *development costs*, 22 J. Health Econ. 151, 166, 180 (2003). A more recent study by economists at the Federal Trade Commission concluded that this $800 million figure probably understated the cost. *See* Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 Health Econ. 130 (2010). And the development costs of bringing a biologic to market are greater still. *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. On Judiciary*, 111th Cong. 2 (2009), http://bit.ly/2ntGgs7 (statement of Mr. Johnson) ("Estimates put average development costs [for new biologics at] as much as $1.37 billion."); *id.* at 221 (statement of Mr. Coble); *id.* at 241 (statement of Mr. Brill).

In these circumstances, a pharmaceutical developer's ability to exercise a temporary monopoly on the sale of its new products is absolutely essential to generate the funds necessary to develop the next generation of treatments. *See, e.g.*, Joseph P. Cook et al., *Generic Utilization Rates, Real Pharmaceutical Prices, and Research and Development Expenditures*, NBER Working Paper 15723, at 19–20 (Feb. 2010), http://www.nber.org/papers/w15723.pdf; F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20 Health Affairs 216 (2001). For that reason, this Court has rightly identified a "significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents.'" *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2006) (citation omitted).

The categorical anti-injunction rule sought by Sanofi would undercut this innovation cycle and subvert the public interest in future drug development by withdrawing injunctive relief from the bundle of rights afforded to patent owners. And it would do so for a class of patents—those awarded to path-breaking, first-in-class therapies—for which the social benefit of patent protection is especially acute.

CONCLUSION

At least with respect to the issues addressed herein, the judgment of the district court should be affirmed.

Respectfully submitted,

/s/ *Melissa Arbus Sherry*

Melissa Arbus Sherry
Michael A. Morin
Emily K. Sauter
LATHAM & WATKINS LLP
555 Eleventh St., NW
Suite 1000
Washington, DC 20004
(202) 637-2200
melissa.sherry@lw.com

Counsel for Amicus Curiae AbbVie Inc.

March 30, 2017

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2017, I caused the foregoing Brief of *Amicus Curiae* in Support of Appellees to be served by electronic means through the Court's CM/ECF system on counsel for all parties who are registered CM/ECF users.

/s/ *Melissa Arbus Sherry*
Melissa Arbus Sherry

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 6,179 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) because this brief was prepared using Microsoft Word 2010 in 14-point Times New Roman font.

Dated: March 30, 2017

/s/ *Melissa Arbus Sherry*
Melissa Arbus Sherry